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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,981	10/31/2003	Sheryl E. Siegel	200.1162US	8850

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
11/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,981	SIEGEL, SHERYL E.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-73 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-73 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22,46-56 and 60, drawn to a method of identifying a drug, classified in class 424, subclass 10.4.

II. Claims 23-27 and 57, drawn to a container, classified in class 53, subclass 52.

III. Claims 28-45 and 58, drawn to a package or kit, classified in class 53, subclass 50.

IV. Claims 61-73, drawn to a business plan, classified in class 434, subclass 107.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-IV are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the method of drug identification does not require the drug be contained in any sort of specific container, be packaged in any specific way or provided by a kit. The method does not require a business method to accomplish its means. The method can be accomplished by the use of an olfactory device such as the human nose. The drug does not need to be contained or packaged in any type of kit. For these reasons the groups are unrelated and restricted.

Inventions II and III-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the invention of group II does not require packaging or kit of group III. The container of group II does not require the

scent masking or closure components of the packaging system. The container also does not require any of the indicia of the kit invention of group III. The container merely requires an enclosed space and a closure mechanism, not a specific scent or engagement means required by the other group III. The container does not require a business method to function and thus is completely unrelated to the business method of group V.

2. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are completely unrelated in that the package or kit of group II does not require a business method in order to function. The business method comprises informing different agencies and organization about the method of identification drug compositions. However none of these business methods impact how a person would use the invention of group III or hoe effective the invention would be at packaging. For these reasons the inventions are unrelated and require restriction.

Species Selection

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species:

7. If group I is selected Applicant is required to make a selection of following species:

a. The species of claims 1,2,48-55 drawn to a method of detecting a scent on a pharmaceutical

b. The species of claims 3,6-10,13-22,46,56 drawn to a method of imparting a scent on a pharmaceutical product

c. The species of claims 4,5,47 drawn to a method of identifying a pharmaceutical product by varying a scent or scent profile

d. The species of claims 11 and 12 drawn to a method of analyzing whether a product is counterfeit

8. The species are independent or distinct because each species requires a mutually exclusive characteristic not required for the other species. Specifically the species described in a. do not require the scent to be imparted to the pharmaceutical product, or being varied or determined whether the product is counterfeit. The species described in b. do not require that the scent be detected, only imparted to the product, and not varied or further analyzed. The species described in c. requires that the scent be varied but not detected by an olfactory device, or actually impart the scent onto a product, or analyze whether the product is counterfeit. The species described in d., requires contacting government agencies something not required by any

other species, the scent need not be varied but is compared to a completely separate composition. The species of group d. requires the scent be absent.

9. Further if the species b. is selected, a selection must be made in claim 10 for the where the scent is being imparted (pharmaceutical product, container, packaging or a combination). If combination is selected from this group a specific combination must be disclosed, claimed and supported by the specification.

10. If group III is selected Applicant is required to make a selection of the following species:

e. The species of claims 28-39 drawn to a packaging system

f. The species of claims 40-45 a kit

11. The species are separate and distinct from one another since the kit species requires more than one scent imparted to the pharmaceutical product. Further the package requires a specific container comprising flanges and specific microencapsulated scent materials, along with opening and closing means, while the kit merely requires a container.

12. If group IV is selected Applicant is required to make a selection of the following species:

g. The species of claim 61, where healthcare officials are informed of the benefits of the method

h. The species of claim 62 where law enforcement agencies are informed of the benefits of the method

i. The species of claim 63 where patients provided with instruction materials

j. The species of claim 64 where law enforcement agencies are provided with instruction materials.

13. The species are separate and distinct from one another since in each species a different group is informed in a different way about the method of the invention. Patients are informed with written instructions, law enforcement personnel are informed via undisclosed means and health acre professionals are informed via separate means. The claims 65-73 are linking claims.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are held as generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is also notified that upon selection of a group and species the claims might be subject to further restriction depending on the selection.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER